CLAIMS

We claim:

1. A conjugate molecule comprising the *E. coli* O157 O-specific polysaccharide, covalently bound to a carrier selected from the group consisting of: the B subunit of Shiga toxin 1, the B subunit of Shiga toxin 2, a non-toxic mutant Shiga toxin 1 holotoxin, and a non-toxic mutant Shiga toxin 2 holotoxin.

2. The conjugate molecule of claim 1 wherein the *E. coli* O157 O-specific polysaccharide is covalently bound to the B subunit of Shiga toxin 1 by means of a dicarboxylic acid dihydrazide linker.

3. The conjugate molecule of claim 2 wherein the dicarboxylic acid dihydrazide is adipic acid dihydrazide.

4. The conjugate molecule of claim 1 wherein the *E. coli* O157 O-specific polysaccharide is covalently bound to the B subunit of Shiga toxin 1 by a process which comprises the steps of

   (a) cyanation of the *E. coli* O157 O-specific polysaccharide with a cyanylation reagent; and

   (b) reaction of the B subunit of Shiga toxin 1 with the resulting cyanated *E. coli* O157 O-specific polysaccharide.

5. The conjugate molecule of claim 4 wherein the cyanylation reagent is 1-cyano-4-(N,N-dimethylamino)pyridinium tetrafluoroborate.

6. A pharmaceutical composition comprising a conjugate molecule of any one of claims 1-5, further comprising a pharmaceutically acceptable carrier.

7. The pharmaceutical composition of claim 6, further comprising an adjuvant.

8. The pharmaceutical composition of claim 6, wherein the composition is capable, upon injection into a mouse of an amount of said composition containing 2.5 μg of *E. coli* O157 O-specific polysaccharide, of inducing in the serum of said mouse antibodies which neutralize the toxicity of Stx1 toward HeLa cells.

9. The pharmaceutical composition of claim 6, wherein the composition is capable, upon injection into a mouse of an amount of said composition containing 2.5 μg of *E. coli* O157 O-specific polysaccharide, of inducing in the serum of said mouse antibodies which neutralize the toxicity of Stx1 toward HeLa cells.

10. A vaccine composition comprising a conjugate molecule, said conjugate molecule comprising the *E. coli* O157 O-specific polysaccharide covalently bound to a carrier protein, in a pharmaceutically acceptable carrier.

11. The vaccine composition of claim 10, wherein the carrier protein is selected from the group consisting of native or mutant forms of: tetanus toxoid, diptheria toxoid, pertussis toxoid, : the B subunit of Shiga toxin 1, the B subunit of Shiga toxin 2, a non-toxic mutant Shiga toxin 1 holotoxin, a non-toxic mutant Shiga toxin 2 holotoxin, *Clostridium perfringens* toxoid, *Clostridium welchii* exotoxin C, *Pseudomonas aeruginosa* recombinant exoprotein A, hepatitis B surface antigen, hepatitis B core antigen, and bovine serum albumin.

12. The vaccine composition of claim 11, wherein the carrier protein is selected from the group consisting of *Clostridium welchii* exotoxin C, *Pseudomonas aeruginosa* recombinant exoprotein A, B subunit of Shiga toxin 1, and bovine serum albumin.

13. The vaccine composition of any one of claims 10 – 12, wherein the composition is capable, upon injection into a human of an amount of said composition containing 25 μg of *E. coli* O157 O-specific polysaccharide, of inducing in the serum of said human bactericidal activity against *E. coli* O157 such that the serum kills 50% or more of *E. coli* O157 at a serum dilution of 1300:1 or more.

14. The vaccine composition of any one of claims 10 – 12, wherein the composition is capable, upon injection into a human of an amount of said composition containing 25 μg of *E. coli* O157 O-specific polysaccharide, of inducing in the serum of said human bactericidal activity against *E. coli* O157 such that the serum kills 50% or more of *E. coli* O157 at a serum dilution of 32,000:1 or more.

15. The vaccine composition of any one of claims 10 – 12, wherein the composition is capable, upon injection into a human of an amount of said composition containing

25 μg of *E. coli* O157 O-specific polysaccharide, of inducing in the serum of said human bactericidal activity against *E. coli* O157 such that the serum kills 50% or more of *E. coli* O157 at a serum dilution of 64,000:1 or more.

16. The vaccine composition of any one of claims 10 – 12, wherein the composition is capable, upon injection into a human of an amount of said composition containing 25 μg of *E. coli* O157 O-specific polysaccharide, of inducing in the serum of said human at least a 50-fold rise in IgG which immunoreacts with *E. coli* O157 LPS, when said IgG is measured 4 weeks post injection.

17. The vaccine composition of any one of claims 10 – 12, wherein the composition is capable, upon injection into a human of an amount of said composition containing 25 μg of *E. coli* O157 O-specific polysaccharide, of inducing in the serum of said human at least a 60-fold rise in IgG which immunoreacts with *E. coli* O157 LPS, when said IgG is measured 26 weeks post injection.

18. The vaccine composition of any one of claims 10 - 12, further comprising an adjuvant.

19. A method of inducing in a mammal serum antibodies that are bacteriostatic or bactericidal to *E. coli* O157, comprising administering to said mammal, in a physiologically acceptable carrier, a conjugate molecule of any one of claims 1-5.

20. The method of claim 18 wherein said conjugate molecule is administered at a dose of about 5 micrograms to about 50 micrograms of *E. coli* O157 O-specific polysaccharide.

21. The method of claim 18 wherein the antibodies protect the mammal against infection by *E. coli* O157.

22. A composition comprising antibodies which are immunoreactive with *E. coli* O157 O-specific polysaccharide.

23. The composition of claim 22, further comprising antibodies which are immunoreactive with the B subunit of Shiga toxin 1.

24. The composition of claim 22, wherein the composition is chosen from the group

consisting of mammalian plasma, mammalian serum, and mammalian gamma globulin fraction.

25. The composition of claim 23, wherein the composition is chosen from the group consisting of mammalian plasma, mammalian serum, and mammalian immunoglobulin fraction.

26. An antibody which is immunoreactive with *E. coli* O157 O-specific polysaccharide.

27. A method of passively immunizing a mammal against *E. coli* O157, comprising administering to said mammal an immunologically sufficient amount of a composition according to any one of claims 22 - 25.

28. The method of claim 27 wherein the antibody is administered at a dose in the range of from about 1 mg/kg to about 10 mg/kg body weight of the mammal.

29. The method of claim 28 wherein the mammal is a human.

30. A method for vaccinating a mammal against *E. coli* O157 infection, comprising administering to the human an immunizing amount of a composition according to claim 6.

31. The method of claim 30 wherein the mammal is a human.

32. A method for vaccinating a mammal against *E. coli* O157 infection, comprising administering to the human an immunizing amount of a vaccine composition according to any one of claims 10 - 12.

33. The method of claim32 wherein the mammal is a human.

34. A conjugate molecule comprising an O-specific polysaccharide, covalently bound to the B subunit of Shiga toxin 1 or Shiga toxin 2, or to a non-toxic mutant Shiga holotoxin, wherein the O-specific polysaccharide is an O-specific polysaccharide of a bacterium chosen from the group consisting of: *E. coli* O157, *E. coli* O111, *E. coli* O17, *E. coli* O26, and *Shigella dyenteriae*.

35. The conjugate molecule of claim 34 wherein the O-specific polysaccharide is covalently bound to the B subunit of Shiga toxin 1 by means of a dicarboxylic

acid dihydrazide linker.

36. The conjugate molecule of claim 35 wherein the dicarboxylic acid dihydrazide is adipic acid dihydrazide.

37. The conjugate molecule of claim 36 wherein the O-specific polysaccharide is covalently bound to the B subunit of Shiga toxin 1 by a process which comprises the steps of

    (a) cyanation of the O-specific polysaccharide with a cyanylation reagent; and

    (b) reaction of the B subunit of Shiga toxin 1 with the resulting cyanated O-specific polysaccharide.

38. The conjugate molecule of claim 37 wherein the cyanylation reagent is 1-cyano-4-(N,N-dimethylamino)pyridinium tetrafluoroborate.

39. A pharmaceutical composition comprising a conjugate molecule of any one of claims 34-37 further comprising a pharmaceutically acceptable carrier.

40. A composition comprising antibodies which are immunoreactive with Shiga toxin 1 or Shiga toxin 2.

41. A method of administering a composition of claim 40 to a mammal in an immunologically sufficient amount.